UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

WYETH,

Plaintiff,

v.

DR. BERNARD M.J. WOLFE,

Defendant.

CIVIL ACTION NO. _____

COMPLAINT FOR DECLARATORY RELIEF

Introduction

Wyeth brings this action for declaratory relief pursuant to 28 U.S.C. § 2201. Wyeth and Defendant, Dr. Bernard M.J. Wolfe ("Wolfe") are parties to a series of agreements by which Wolfe granted to Wyeth a license under certain patent rights related to hormone replacement therapy for the treatment of menopause symptoms. Wolfe recently filed a civil action in the Superior Court of Justice of Ontario, Canada in which he alleges, among other things, that Wyeth has breached the parties' agreements and breached a fiduciary duty it allegedly owed Wolfe by misappropriating Wolfe's confidential information. In this action, Wyeth seeks a declaratory judgment that Wyeth did not misappropriate any confidential information of Wolfe's in breach of the agreements or otherwise; and further, that any breach of contract, breach of fiduciary duty or misappropriation claim against Wyeth related to the subject matter of the parties' agreements is barred by the applicable Pennsylvania Statute of Limitations.

THE PARTIES

1. Wyeth, formerly American Home Products Corp. ("Wyeth"), is a corporation organized and existing under the laws of the State of Delaware, and has a place of business at 5 Giralda Farms, Madison, New Jersey. Wyeth's Pharmaceutical Division has a place of business at 500 Arcola Road, Collegeville, Pennsylvania.

2. On information and belief, Defendant Wolfe resides at 17 Metamara Cres., London, Ontario N6G 1R2, Canada and is a retired professor at the University of Western Ontario.

JURISDICTION & VENUE

3. This Court has jurisdiction in this matter pursuant to 28 U.S.C. § 1332(a) because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

4. This Court has personal jurisdiction over the defendant pursuant to 42 Pa. Cons. Stat. § 5322 because Wolfe entered into several agreements with Wyeth that related to a product developed by Wyeth's Pharmaceutical Division located in this district, and Wolfe regularly visited this district in connection with the parties' agreements.

5. Venue in this district is proper pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events, acts and omissions giving rise to Wyeth's claims occurred in this district.

6. An actual controversy exists for purposes of the Declaratory Judgment Act, 28 U.S.C. § 2201, with respect to whether Wyeth breached the parties' agreements, misappropriated Wolfe's confidential information and/or breached a fiduciary duty owed to Wolfe.

FACTS

Hormone Replacement Therapy

7. Hormone replacement therapy ("HRT") often is prescribed to menopausal or postmenopausal women to relieve various physiological symptoms that can occur during menopause. In particular, the administration of pharmaceutical compositions containing estrogen or estrogen-like hormones has been found to be highly effective in treating symptoms of menopause.

8. Wyeth has been a pioneer in the development of novel HRT for the treatment of the menopause symptoms suffered by many women. Premarin, the first FDA-approved orally active estrogen replacement therapy, was developed by Wyeth scientists in the 1930s. Since its commercial introduction in 1942, Premarin has helped millions of women suffering from the most serious effects of menopause.

9. After the introduction of Premarin, Wyeth scientists began investigating an HRT that included a combination of Premarin with a progestin, another hormone that was thought to reduce the risk of endometrial hyperplasia that could result from therapy with estrogen alone. That research led to the commercial introduction of PremPro™ in 1995. PremPro™ combines Premarin with the progestin replacement known as medroxyprogesterone acetate ("MPA"). This combination quickly became one of the leading HRT treatments for moderate to severe menopausal symptoms.

The Agreements

10. Wolfe and Dr. Earl Plunkett ("Plunkett") are co-inventors of the invention disclosed and claimed in United States Patent No. 4,826,831 (the "'831 patent"). The '831 patent generally is directed to HRT methods and compositions for treating menopausal disorders in women. The '831 patent specifically describes and claims methods of treating menopausal and

postmenopausal disorders by administering both estrogen and progesterone. The '831 patent issued on May 2, 1989. It was reissued with narrower claims on July 6, 1999, and it expired on May 2, 2006.

11. On January 1, 1991, Wyeth entered into an Option Agreement with Wolfe. The Option Agreement was designed to allow Wyeth to evaluate and develop the invention described and claimed in the '831 patent. Wyeth was also granted the exclusive option to license the '831 patent and related know-how.

12. On December 9, 1992, Wyeth and Wolfe entered into two License Agreements (which were amended and restated as of April 1, 2000) (the "License Agreements"). The License Agreements granted Wyeth exclusive rights to make, have made, use and sell products under the '831 patent and its foreign counterparts and related know-how. In exchange for the licenses, Wyeth agreed to pay to Wolfe and Plunkett royalties on its sales of products covered by the claims of the '831 patent and its foreign counterparts until expiration of the patents. Since the introduction of PremPro™ in 1995, Wyeth has paid Wolfe millions of dollars in royalties associated with sales of its HRT products.

13. Under the License Agreements and the Option Agreement, Wolfe retained the right to conduct his own independent research concerning HRT generally. Wyeth also was free to conduct its own HRT research without restriction. To the extent that either developed any intellectual property as a result of independent research, each retained sole ownership of that intellectual property (subject to Wyeth's right to exercise its option to license Wolfe's intellectual property under the Option Agreement).

Wyeth's Independent Development of Low-Dose HRT

14. One of Wyeth's objectives in its ongoing HRT research was to further improve the treatment. Wyeth scientists believed that one way to reduce the risk of endometrial hyperplasia would be to lower the amounts of estrogen and progestin administered to patients to the lowest effective dose that would still achieve the desired clinical benefit. Therefore, Wyeth scientists experimented with formulations of Premarin and MPA that contained less than the 0.625 mg of Premarin and the 2.5 mg of MPA in the original PremPro™ combination.

15. By early 1992, a team of Wyeth scientists led by Dr. James Pickar had begun to develop a protocol for a low dose Premarin/MPA clinical study. In the study, Dr. Pickar planned to test various combinations of Premarin and MPA with the objective of identifying the lowest effective dose of the combined therapy.

16. In 1992 and 1993, Dr. Pickar and his team worked to refine the clinical protocol for low-dose combination therapy. All of this work was conducted entirely by Wyeth scientists. The defendant, Wolfe, was not consulted, nor was he involved in any way in assisting Wyeth, in connection with these clinical development efforts.

17. Ultimately, Wyeth submitted to the United States Food and Drug Administration ("FDA") a protocol synopsis developed by Dr. Pickar entitled "A Prospective, Double-Blind, Randomized Study of the Safety and Efficacy of Lower Doses of Premarin and Medroxyprogesterone Acetate in Postmenopausal Women." The purpose of Dr. Pickar's study was to determine the minimum effective dose of the combination of Premarin and MPA for the treatment of menopause symptoms which also would be effective in reducing the incidence of

endometrial hyperplasia associated with the administration of estrogen alone. The eight doses proposed were:

Premarin 0.625 mg
Premarin 0.45 mg
Premarin 0.3 mg
Premarin 0.45 mg/MPA 2.5 mg
Premarin 0.625 mg/MPA 2.5 mg
Premarin 0.45 mg/MPA 1.5 mg
Premarin 0.3 mg/MPA 1.5 mg

18. This low dose Premarin/MPA study developed by Dr. Pickar and his team at Wyeth, and subsequently submitted to the FDA for approval, was named the Health and Osteoporosis, Progestin and Estrogen (H.O.P.E.) Study. The H.O.P.E. Study was completed in or about 1998. The results later were reported in several publications. Wyeth did not consult with Wolfe nor utilize any information provided by Wolfe in connection with the design or implementation of the H.O.P.E. Study.

Wyeth's HRT Patents

19. Wyeth learned from the H.O.P.E. study that doses as low as 0.3 mg of Premarin combined with 1.5 mg of MPA remained effective in treating the symptoms of menopause for many women. These lower doses were successful in preventing osteoporosis and reducing the risk of endometrial hyperplasia.

20. On March 15, 2001, Wyeth filed Patent Application No. 09/808,878 (the '878 Application) with the United States Patent and Trademark Office (the "PTO"). The '878 Application described Dr. Pickar's breakthrough development of a low-dose HRT. Specifically, it sought protection for various low-dose combinations of conjugated estrogens like Premarin administered with MPA. Wyeth did not name Wolfe as an inventor on the '878 Application because he had not contributed to Dr. Pickar's invention as disclosed in the application. The

'878 Application remains pending in the PTO, but has not yet issued as a patent in the United States.

21. Wyeth has filed patent applications corresponding to the '878 Application in various countries throughout the world. To date, patents have been granted on Dr. Pickar's invention in several countries. Patent applications remain pending in other jurisdictions, including the United States and Canada.

Wolfe's Claims

22. The results of the H.O.P.E. Study were first reported in two papers published in June of 2001. The '878 Application, which had been filed in March 2001 (based on a provisional patent application filed in March 2000), published on October 25, 2001. In December 2001, apparently after seeing the '878 Application, Wolfe contacted Wyeth and claimed that he should have been named as inventor on the '878 Application. Wolfe said that he believed he had given Wyeth the idea for the dosage combinations disclosed in Dr. Pickar's patent application. Also, in late 2001 and early 2002, Wolfe and his attorneys told Wyeth that they believed Wolfe's confidential information had been included in the '878 Application.

23. Wolfe's claim to inventorship is based on his assertion that the '878 Application contains information about low-dose HRT that Wolfe contends he developed in the course of a clinical study that he and his associates had conducted at the University of Western Ontario. In his study, Wolfe had administered 0.625 mg doses of Premarin in combination with .050 mg doses of *dl*-norgestrel, a different progestin substitute than MPA. The goal of Wolfe's study was to examine the effect of his combination on plasma lipoprotein lipids (e.g., cholesterol and triglycerides in the blood). His hypothesis was that his combination would be effective in treating menopause symptoms and would also have the beneficial cardiovascular effect of improving plasma lipid profiles.

24. Wolfe had conducted his study in or about 1992 – 1994. He published his results in April 1998.

25. During the period from 1992 – 1994, while Wolfe was conducting his study, he communicated with various Wyeth representatives in Pennsylvania periodically. Also, as contemplated in the License Agreement with Wyeth, he traveled to Wyeth's facility in Radnor, Pennsylvania on several occasions to discuss the clinical development of HRT. There were no such meetings in Ontario.

26. Wolfe does not now claim, nor could he, that his clinical study was designed to evaluate the lowest effective dose of the Premarin/*dl*-norgestrel combination. Rather, as Wolfe's publications concerning his study make quite clear, his objective was different – i.e., to evaluate an improved plasma-lipid profile using different progestins. He now has claimed, however, without any scientific support, that the .050 mg dose of *dl*-norgestrel used in his study was equivalent to the 1.5 mg of MPA used by Dr. Pickar in the H.O.P.E. Study. Consequently, because he provided information to Wyeth concerning his study, he asserts that he should have been named as an inventor on Dr. Pickar's patents and patent applications.

27. From early 2002 until September 2007, Wolfe and Wyeth engaged in periodic discussions concerning Wolfe's contention that he should have been named as an inventor on the Pickar patents. Throughout these discussions, Wyeth made it clear that it had reviewed the matter and concluded that Wolfe had not contributed to Dr. Pickar's invention as described in the '878 Application, and that, as a result, he properly was not listed as an inventor.

28. On September 27, 2007, Wolfe commenced two proceedings against Wyeth in Canada. In one of these cases, filed in the Canadian Federal Court, Wolfe seeks an order that Wyeth's Canadian Patent Application No. 2,402,983 (which corresponds to the '878 Application

filed in the U.S.) be amended to list Wolfe as the sole inventor. In the second action, filed in the Ontario Superior Court of Justice (the "Ontario Action"), Wolfe alleges that Wyeth breached the parties' agreements, including the License and Option Agreements, and misappropriated Wolfe's confidential information by incorporating into Dr. Pickar's patent applications the Premarin/MPA combination allegedly invented by Wolfe. In the Ontario Action, Wolfe seeks compensatory and punitive damages purportedly arising from Wyeth's global exploitation of the inventions described and claimed in Dr. Pickar's patents and patent applications.

29. The vast majority of the alleged damages sought by Wolfe in the Ontario Action relate to activities in the United States, where nearly all of Wyeth's sales of low-dose PremPro™ have occurred. Significantly, low-dose PremPro™ is not even offered for sale in Canada.

COUNT I
(Declaratory Judgment)

30. Wyeth realleges, and incorporates by reference, the allegations contained in paragraphs 1 to 29 above.

31. Wolfe has alleged in his Canadian proceedings that Wyeth disclosed confidential information regarding Wolfe's alleged invention of a low dose Premarin/MPA formulation for the treatment of menopausal or postmenopausal disorders in breach of the parties' agreements. Specifically, Wolfe alleges that Wyeth improperly disclosed his confidential information in Dr. Pickar's United States patent application, which was published on October 25, 2001.

32. In fact, Wyeth did not disclose Wolfe's confidential information in the '878 Application or otherwise violate its contractual obligations to Wolfe.

33. Wolfe's breach of contract claims asserted in the Ontario Action properly are subject to Pennsylvania's four-year statute of limitations pursuant to 42 Pa. Cons. Stat. § 5525, and, therefore, are time-barred.

34. Based upon Wolfe's allegations in the Ontario Action, an actual controversy exists as to whether Wyeth has breached the parties' agreements.

35. Pursuant to 28 U.S.C. § 2201, Wyeth is entitled to a declaration by this Court regarding: (1) whether it has breached the parties' agreements and (2) whether any breach of contract claim brought by Wolfe is barred by the applicable statute of limitations.

COUNT II
(Declaratory Judgment)

36. Wyeth realleges, and incorporates by reference, the allegations contained in paragraphs 1 to 35 above.

37. Wolfe has alleged in his Canadian proceedings that Wyeth misappropriated Wolfe's confidential information regarding Wolfe's alleged invention of a low dose Premarin/MPA formulation for the treatment of menopausal or postmenopausal disorders. Specifically, Wolfe alleges that Wyeth improperly incorporated his confidential information in Dr. Pickar's United States patent application, which was filed on March 15, 2001 and published on October 25, 2001.

38. In fact, Wyeth did not improperly use Wolfe's confidential information in the '878 Application or otherwise.

39. Wolfe's misappropriation claims asserted in the Ontario Action properly are subject to Pennsylvania's two-year statute of limitations pursuant to 42 Pa. Cons. Stat. § 5524(7) and, therefore, are time barred.

40. Based on Wolfe's allegations in the Ontario Action, an actual controversy exists as to whether Wyeth has misappropriated Wolfe's confidential information.

41. Pursuant to 28 U.S.C. § 2201, Wyeth is entitled to a declaration by this Court regarding: (1) whether Wyeth has misappropriated any of Wolfe's confidential information and

(2) whether any misappropriation claim brought by Wolfe is barred by the applicable statute of limitations.

COUNT III
(Declaratory Judgment)

42. Wyeth realleges, and incorporates by reference, the allegations contained in paragraphs 1 to 41 above.

43. Wolfe has alleged in his Canadian proceedings that Wyeth breached a fiduciary duty it allegedly owed to Wolfe by misappropriating Wolfe's confidential information regarding Wolfe's alleged invention of a low dose Premarin/MPA formulation for the treatment of menopausal or postmenopausal disorders.

44. In fact, Wyeth does not owe Wolfe any such fiduciary duty and, in any event, Wyeth did not breach any fiduciary obligations to Wolfe in connection with the parties' agreements or otherwise.

45. Wolfe's breach of fiduciary duty claims asserted in the Ontario Action properly are subject to Pennsylvania's two-year statute of limitations pursuant to 42 Pa. Cons. Stat. § 5524(7) and, therefore, are time barred.

46. Based on Wolfe's allegations in the Ontario Action, an actual controversy exists as to whether Wyeth has breached any fiduciary duty owed to Wolfe.

47. Pursuant to 28 U.S.C. § 2201, Wyeth is entitled to a declaration by this Court regarding: (1) whether Wyeth has breached any fiduciary duty owed to Wolfe and (2) whether any breach of fiduciary duty claim brought by Wolfe is barred by the applicable statute of limitations.

WHEREFORE, Wyeth prays for judgment against Wolfe as follows:

(a) declaring that any breach of contract claim Wolfe may have against Wyeth is barred by the Pennsylvania Statute of Limitations;

(b) declaring that any misappropriation claim Wolfe may have against Wyeth is barred by the Pennsylvania Statute of Limitations;

(c) declaring that any breach of fiduciary duty claim Wolfe may have against Wyeth is barred by the Pennsylvania Statute of Limitations;

(d) declaring that Wyeth has not breached the License Agreement, the Option Agreement, or any other agreement with Wolfe;

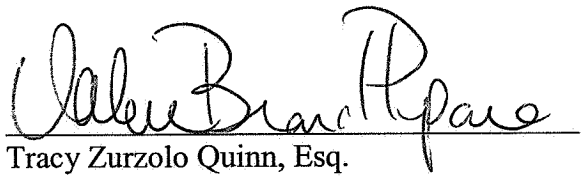
(e) declaring that Wyeth has not misappropriated any confidential information or trade secrets of Wolfe;

(f) declaring that Wyeth has not breached any fiduciary duty owed to Wolfe; and

(g) awarding Wyeth its attorneys' fees, costs and any further and additional relief as this Court deems just and proper.

Respectfully submitted,

WYETH,



Tracy Zurzolo Quinn, Esq.
Michael T. Scott, Esq.
Valerie Brand Pipano, Esq.
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103

Dated: February 15, 2008

Of Counsel:

Eric J. Marandett, Esq.
E. Page Wilkins, Esq.
Choate, Hall & Stewart
Two International Place
Boston, MA 02110
Tel: 617-248-5000
Fax: 617-248-4000

APPENDIX G

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

WYETH	:	
	:	
V.	:	Civil Action
	:	No: _____
DR. BERNARD M.J. WOLFE	:	

DISCLOSURE STATEMENT FORM

Please check one box:

☒ The nongovernmental corporate party, Wyeth, in the above listed civil action does not have any parent corporation and publicly held corporation that owns 10% or more of its stock.

☐ The nongovernmental corporate party, _____, in the above listed civil action has the following parent corporation(s) and publicly held corporation(s) that owns 10% or more of its stock:

_____
_____
_____
_____

February 15, 2008
Date

Signature

Counsel for: Wyeth

Federal Rule of Civil Procedure 7.1 Disclosure Statement

(a) WHO MUST FILE: NONGOVERNMENTAL CORPORATE PARTY. A nongovernmental corporate party to an action or proceeding in a district court must file two copies of a statement that identifies any parent corporation and any publicly held corporation that owns 10% or more of its stock or states that there is no such corporation.

(b) TIME FOR FILING; SUPPLEMENTAL FILING. A party must:

(1) file the Rule 7.1(a) statement with its first appearance, pleading, petition, motion, response, or other request addressed to the court, and

(2) promptly file a supplemental statement upon any change in the information that the statement requires.